UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

FILED

JUL 24 2008

U. S. DISTRICT COURT
EASTERN DISTRICT OF MO

UNITED STATES OF AMERICA,

Plaintiff,

v.

Various quantities of articles of drug, finished drug products, listed as follows:

PhenaVent Capsules
PhenaVent LA Capsules
PhenaVent PED Capsules
Ethezyme Papain-Urea Ointment
Ethezyme 650 Papain-Urea Ointment
Ethezyme 830 Papain-Urea Ointment
Hista-Vent DA Tablets
Meperidine/Promethazine Capsules
Pseudovent Capsules
Pseudovent 400 Capsules
Pseudovent PED Capsules
Tri-Vent DM Syrup
Tri-Vent DPC Syrup
Hydro-Tussin DM Liquid
Hydro-Tussin CBX Syrup
Hydro-Tussin DHC Syrup
Hydro-Tussin EXP Syrup
Hydro-Tussin HD Syrup
Hyoscyamine Sulfate Sublingual Tablets
Hydroquinone 4% Cream
Hydroquinone 4% Cream with Sunscreen
Bromfenex Extended Release Capsules
Bromfenex PD Extended Release Capsules

Various quantities of articles of drug, in-process drug products, listed as follows:

PhenaVent LA Capsules
Hydroquinone 4% Cream with Sunscreen
Hydroquinone 4% Cream

and

all other articles of drug (excluding bulk drugs), identified above, in any size and type of container, labeled or unlabeled (regardless of identification as to lot, batch, control number, production date, or expiration date), which are located anywhere on the premises of KV Pharmaceutical Company, 3100 Corporate Exchange Court, Bridgeton, Missouri, #1 Corporate Woods Drive, Earth City

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(Bridgeton), Missouri, or elsewhere within the jurisdiction of this Court, which consist in whole or in part of components that originated outside the State of Missouri,

Defendants.

VERIFIED COMPLAINT FOR FORFEITURE

Comes now plaintiff, United States of America, by and through its attorneys, Catherine L. Hanaway, United States Attorney for the Eastern District of Missouri, and Andrew J. Lay and Suzanne J. Moore, Assistant United States Attorneys for said district, and seeks civil forfeiture of the articles of drug described in the caption under the provisions of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 301 et seq., stating as follows:

NATURE OF THE ACTION

1. This complaint is filed by the United States of America, and requests seizure and condemnation of articles of drug, as described in the caption, in accordance with the Act.

2. In Bridgeton, Missouri, in the possession of KV Pharmaceutical Company, 3100 Corporate Exchange Court and #1 Corporate Woods Drive, Bridgeton, Missouri, or elsewhere within the jurisdiction of this Court, there are articles of drug, which articles consist in whole or in part of one or more components that were shipped in interstate commerce from outside the State of Missouri.

JURISDICTION AND VENUE

3. Plaintiff brings this action in rem in its own right to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the Court with jurisdiction over seizures brought under the Act.

4. This Court has in rem jurisdiction over the defendant property because the defendant is located in the Eastern District of Missouri. Upon filing of the complaint, the plaintiff requests the Court issue an arrest warrant in rem pursuant to Supplemental Rule G(3)(b), which the plaintiff will execute upon the property pursuant to Supplemental Rule G(3).

5. Venue is proper in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant property is located at KV Pharmaceutical Company, 3100 Corporate Exchange Court and #1 Corporate Woods Drive, Bridgeton, Missouri, and 2303 Schuetz Road, Maryland Heights, Missouri.

BASIS FOR FORFEITURE

6. The articles (all lots) are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

7. The articles (all lots) are drugs that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. 355(a) in that they are new drugs within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) are in effect for such drugs.

8. The articles (all lots) are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 CFR 201.115 since they are unapproved new drugs.

9. In light of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to the provisions of 21 U.S.C. § 334.

FACTS

10. KV Pharmaceutical Company ("KV") is a manufacturer of drug products for human use. The firm receives and holds many drug components that have been shipped to it in interstate commerce and uses them to manufacture numerous drug products, which are held for sale. Many of KV's finished drug products are introduced into interstate commerce.

11. In a Federal Register Notice of May 29, 2007 (72 Fed. Reg. 29517 (May 29, 2007)), FDA announced its intention to take enforcement action against unapproved, timed-release drug products containing guaifenesin and persons who cause the manufacture or interstate shipment of these products. This Notice stated that timed-release drug products containing guaifenesin require approved new drug applications because they are "new drugs," in accordance with 21 CFR 310.502(a)(14). Furthermore, the FDA Notice required firms to stop manufacturing these products before August 27, 2007, and to stop shipping the products in interstate commerce before November 26, 2007. The FDA Notice also clearly stated that if a firm continues to manufacture or market a product covered by this notice after the applicable enforcement date has passed, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications, whether or not the articles were specifically identified in the FDA Notice. See Ex. 1 hereto.

12. FDA inspected KV's facilities in Bridgeton, Missouri during January 30 - March 26, 2008. This FDA inspection revealed that the firm continued to manufacture and distribute timed-release drug products containing guaifenesin beyond the cessation dates set forth in the FDA

Notice, namely PhenaVent Capsules, PhenaVent LA Capsules, PhenaVent PED Capsules, Pseudovent Capsules, Pseudovent 400 Capsules, and Pseudovent PED Capsules.

13. FDA's inspection of KV's facilities also found that KV was manufacturing and marketing many other unapproved new drugs, including Ethezyme Papain-Urea Ointment, Ethezyme 650 Papain-Urea Ointment, Ethezyme 830 Papain-Urea Ointment, Hista-Vent DA Tablets, Meperidine/Promethazine Capsules, Tri-Vent DM Syrup, Tri-Vent DPC Syrup, Hydro-Tussin DM Liquid, Hydro-Tussin CBX Syrup, Hydro-Tussin DHC Syrup, Hydro-Tussin EXP Syrup, Hydro-Tussin HD Syrup, Hyoscyamine Sulfate Sublingual Tablets, Hydroquinone 4% Cream, Hydroquinone 4% Cream with Sunscreen, Bromfenex Extended Release Capsules, and Bromfenex PD Extended Release Capsules. Hista-Vent DA Tablets, Bromfenex Extended Release Capsules, and Bromfenex PD Extended Release Capsules all require approved new drug applications because they are "new drugs," in accordance with 21 CFR 310.502(a)(14). The remaining products discussed in this paragraph are "new drugs" within the meaning of 21 U.S.C. § 321(p) and also require approved new drug applications.

14. In accordance with its stated policy in the FDA notice, FDA is therefore taking enforcement action against the above-captioned illegally marketed unapproved new drugs.

REQUESTED RELIEF

15. Plaintiff, the United States of America, respectfully requests that a warrant for arrest issue against the defendant articles set forth in the Attachment hereto; that this Court decree the condemnation of the defendant articles and grant plaintiff the costs of this proceeding against the claimant of the defendant articles; that the defendant articles be disposed of as this Court may

direct pursuant to the provisions of the Act; and that the plaintiff have such other and further relief as the case may require.

Respectfully submitted,

CATHERINE L. HANAWAY
UNITED STATES ATTORNEY

By: _____

Suzanne J. Moore #40119
Andrew J. Lay #28542
Assistant United States Attorney
Eastern District of Missouri
111 South Tenth Street, Room 20.333
St. Louis, Missouri 63102
Telephone: 314-539-2200

VERIFICATION

I, CLARENCE R. PENDLETON, hereby verify and declare under penalty of perjury that I am the Director of Compliance, U.S. Food and Drug Administration (FDA) Kansas City District Office, that I have read the foregoing verified complaint for forfeiture and know the contents thereof, and that the matters contained in the verified complaint are true to my own knowledge, except that those matters herein stated to be alleged on information and belief and as to those matters I believe them to be true.

The sources of my knowledge and information and the grounds for my belief are the official files and records of FDA, as well as my investigation of this case, together with information provided to me from other FDA employees.

I hereby verify and declare under penalty or perjury that the foregoing is true and correct.

Dated: St. Louis, Missouri
6/26/2008

CR Pendleton

CLARENCE R. PENDLETON
Director of Compliance
Kansas City District Office
Food and Drug Administration

ATTACHMENT

FINISHED PRODUCT	Inventory/Units	Location
PhenaVent Caps 30's	21232.00	EC2
PhenaVent LA Caps 30's	90982.00	EC2
PhenaVent PED Caps 100's	10816.00	EC2
Ethezyme Papain-Urea Ointment	5115.00	EC2
Ethezyme 650 Papain-Urea Ointment	34641.00	EC2
Ethezyme 830 Papain Urea Ointment	33217.00	EC2
Hist-Vent DA Tabs 100's	27754.00	EC2
Meperidine/Promethazine Caps 1	22636.00	EC2
Pseudovent Caps 100's	5387.00	EC2
Pseudovent 400 Caps 100's	48248.00	EC2
Pseudovent PED Caps 100's	9839.00	EC2
Tri-Vent DM Syrup 16 oz	13435.00	EC2
Tri-Vent DPC Liquid 16 oz	7714.00	EC2
Hydro-Tussin DM Liquid 16 oz	395.00	EC2
Hydro-Tussin CBX Liquid 16 oz	1365.00	EC2
Hydro-Tussin DHC Syrup 16 oz Cl	3969.00	EC2
Hydro-Tussin EXP Liquid 16 oz Cl	3871.00	EC2
Hydro-Tussin HD Liquid 16 oz Cl	4.00	EC2
Hyoscyamine Sublingual Tabs 0.125 mg 100's	23110.00	EC2
Hydroquinone 4% Cream 1 oz	16901.00	EC2
Hydroquinone 4% Creams 1 oz with Sunscreen	10636.00	EC2
Bromfenex ER Caps 100's	8261.00	EC2
Bromfenex PD ER Caps 100's	8834.00	EC2
FINISHED PRODUCT BULK IN-PROCESS	**Inventory**	**Location**
Phenavent LA Caps	464644 capsules	EC4
Hydroquinone 4% cream with sunscreen 1 oz	4056 tubes	EC4
Hydroquinone 4% cream 1 oz	17 boxes-bulk	EC4
	approx. 4000 tubes	
EC2 = Logistics Warehouse 3100 Corporate Exchange Court, Bridgeton, MO		
EC4 = #1 Corporate Woods Drive, Bridgeton, MO		